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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,860	04/16/2002	Peter James Brian Lamb	ADMS-0003	8533
23377	7590	08/04/2005		
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			EXAMINER GIBSON, KESHIA L	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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10/031,860

EXAMINER

ART UNIT

PAPER

20050726

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Office Action Summary

Application No.

10/031,860

Applicant(s)

LAMB, PETER JAMES BRIAN

Examiner

Keshia Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/23/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see paragraphs 5, 8 and 9 page 2, filed 5/23/2005, with respect to the rejection(s) of claim(s) 1 and 3-15 under Rademaker et al. (US 5,397,312), Paul et al. (US 5,158,535), Rademaker in view of KenKnight (US 5,314,464), and Rademaker in view of Paul et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gamache, Jr. et al (US 1,224,735) and Grant (US 61,417).

Applicant has essentially argued that neither Rademaker et al. nor Paul et al, both serving as base references for all rejections, taught the newly added claim limitation of a "straight" barrel. The term "straight" has been considered to mean "free from curves." Upon review of the stated prior art, the examiner has agreed with the applicant's arguments. However, the addition of the limitation of a "straight" barrel was necessitated new grounds of rejection, provided below.

2. Applicant's arguments filed 5/23/2005 have been fully considered but they are not persuasive.

In regard to Claim 2, applicant has argued that Rademaker et al. disclose an applicator for use with a cream substance, which cannot be considered a solid object. However, the applicator of Rademaker et al. only need be capable of providing such a function. For example, any pill of appropriate size can be deposited into the chamber of

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the barrel of the applicator then be pushed out of the barrel outlet and into a body cavity. Thus, the applicator of Rademaker et al. is considered capable of depositing a solid object.

In regard to Claim 15, the applicant has argued that the petals of Paul et al. cannot bend inward because the presence of a tampon would prevent them from doing so. However, as stated in the previous action, the petals are thin flexible members capable of being bent outward due to forces being applied from the expulsion of the tampon. Thus, the petals are also inherently capable for being bent inward due to forces being applied due to insertion. The tampon does not occupy all the space within the cavity; there is still space for the petals to fold inward when the appropriate amount of force is applied. Also, the grooves, or spaces, between the petals allow for additional mobility of the petals as well as additional areas into which the petals can bend. As such, the applicator of Paul et al. is still considered to have parts surrounding the barrel outlet that displaceable toward each other.

Despite applicant's arguments, Rademaker et al. and Paul et al. are still considered to anticipate or render obvious the limitations set forth in Claims 2 and 15 of the claimed invention, as presented in the previous Office Action (which has been modified and presented again, in view of applicant's amendments, below).

Interpretations/Definitions

In Claims 2 and 4, the applicant has required that the barrel be "penile-shaped" in cross section but has not referenced an axis about which the cross section should be taken or

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the area of the penis to which the term is to refer. The examiner has considered the term "penile-shaped" to include a cross section taken along any axis of any portion of any type of penis, which would include the cylindrical shaft of a penis.

Claim Objections

3. Claim 13 is objected to because of the following informalities: the "gripping surfaces" lack proper antecedent basis; it is suggested that this term be changed to "gripping portion." Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1-4, 1-8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gamache, Jr. et al. (US 1,224,785).

In regard to Claims 1 and 3, Gamache, Jr. et al. disclose a device for inserting a medicament 28 into the vagina, the device comprising an elongate body 21/25 having a gripping portion 25, a straight barrel 21, a passage 29, and a plunger 25 (Figs. 1-16; page 1, lines 20-51; page 2, lines 55-104). The passage 29 is curved in the gripping portion, has an outlet (opening near end edges of barrel 21 near medicament 28), and

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is linear in the barrel portion (Figs. 1-2, 4-8, 12). The medicament 28 is disclosed as being a medicated tampon (page 2, lines 69-73).

In regard to Claim 2, as discussed for Claims 1 and 3, the device comprising an elongate body 21/25 having a gripping portion 25, a barrel 21, a passage 29, and a plunger 25 (Figs. 1-16; page 1, lines 20-51; page 2, lines 55-104). The barrel may be cylindrical or elliptical in shaper and is therefore considered to be "penile-shaped" in cross-section (Figs. 3, 5, 6, 11, 13, 15, and 17). A portion for the passage 29 spaced from the outlet is curved in a longitudinal direction (Figs. 1-2, 4, 8, and 12).

In regard to Claim 4, the barrel is elongate and cylindrical in nature and is therefore considered to be "penile-shaped."

In regard to Claim 7, the outlet end portion (i.e., portion of the barrel 21 near the outlet) has a cross-section that is cylindrical or elliptical in nature and is therefore considered to be "penile-shaped."

In regard to Claim 8, the passage 29 includes a chamber 36 for receiving the medicament (Fig. 1-2, 4, 8, 12; page 2, lines 85-104).

In regard to Claim 10, the barrel 21 includes a slit 22 through which a string 32 of a tampon 28 received in the passage 29 can protrude (Figs. 2-8, 10-11, 15; page 2, lines 56-104; page 3, lines 55-61).

6. Claims 1, 3-4, 7-9, and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grant (US 61,417).

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In regard to Claims 1 and 3, Grant discloses a device (director A) for depositing an object (pessary) into the vagina. The device has an elongate body with a straight barrel, a gripping portion (ends of the device A opposing ends C to be inserted into the vagina), a linear passage (open area between the device A walls), and a plunger E/F (Figs. 1-2; lines 23-49). The passage has an outlet at the free end C of the barrel (Fig. 1; lines 26-35). The barrel is a tube and therefore cylindrical in nature; as such, the passage is considered to be curved (Figs. 1-2; lines 23-25). (It is pointed out that the "longitudinal direction" can currently be defined in any arbitrary location.)

In regard to Claim 4, the barrel is elongate and cylindrical in nature and is therefore considered to be "penile-shaped."

In regard to Claim 7, the outlet end portion C has a cross-section that is cylindrical in nature and is therefore considered to be "penile-shaped."

In regard to Claim 8, the passage of the device can be considered a chamber. The passage (chamber) receives an object D (Figs. 1-2; lines 27-35).

In regard to Claim 9 and 15, the chamber is spaced from the outlet (near C) allowing the sides of the barrel C above and below the outlet to be displaced toward each other, partially closing off the outlet (Figs. 1-2; lines 29-40).

In regard to Claim 14, the body B, B of the device A is monolithic (Figs. 1-2). Again, the term "moulded" is considered to be a product-by-process limitation; therefore it has been given little patentable weight.

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7. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Rademaker et al. (US 5,397,312).

In regard to Claim 2, Rademaker et al. disclose an applicator for inserting a medicament into a vagina; the applicator has an elongate body (Fig. 1), an elongate barrel 1 with a passage (extending from chamber 4 to front end of control button 19), and a plunger 2. A portion of the passage spaced from the outlet is curved (Figs. 1 and 2, column 2, lines 52-61). The passage extends through the elongate body, has an outlet 3 at the free end of the barrel, and is capable of receiving a nonflowable object or medicament. The plunger 2 can be displaced along the passage to push a medicament in the passage through the outlet 3 into the user's vagina (column 3, line 67- column 4, line 60). The barrel is elongate and cylindrical in nature and is therefore considered to be "penile-shaped."

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 5-6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamache et al.

In regard to Claims 5-6, the passage has an inlet (opening near element 35) remote from its outlet (opening near end edges of barrel 21 near medicament 28). The curved portion of the passage renders a centrally disposed longitudinal axis (running parallel to the sides of barrel 21) of the barrel 21 and a centrally disposed axis (running parallel to the side edges of gripping portion 25) through the inlet at an obtuse angle (Figs. 1-2, 4, 8, and 12). Thus, Gamache et al. teach that the barrel and the passage are at an obtuse angle relative to each other. Gamache et al. do not expressly disclose that the obtuse angle created by these axes is between angles of specific degrees. However, the angle between the two axes would affect the user's ability to insert the applicator into a body cavity unassisted. Because the angles created between the axes affect the ability of the user to insert the device into a body cavity unassisted, these angles are considered to be result effective variables. Thus, it would have been obvious to one of ordinary skill in the art to provide the device with the obtuse angle created by these axes being between angles of specific degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regard to Claim 13, the applicator is gripped at the gripping portion 25 between five fingers of one hand; the areas corresponding to the middle and index fingers lie within

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the same horizontal plane (Fig. 14; page 3, line 95-page 4, line 44). Thus, Gamache, Jr. et al. disclose the claimed invention but do not expressly disclose that the device is gripped between the fingers in such a manner that the barrel projects upward from the horizontal plane at an angle between 45 and 10 degrees. However, Gamache, Jr. et al. do disclose that the barrel and the horizontal plane are at an acute angle relative to each other (Figs. 1-2, 4, 8, 11, and 16). Also, the angle provided between the barrel and the gripping portion would affect the ability of the applicator to be inserted into a vagina, or other body cavity, and would also affect the ability of the user to effectively insert to the applicator into the vagina (or other body) unassisted. Thus, the angle at which the barrel projects upward relative to the gripping portion is considered a result effective variable. It would have been obvious to one of ordinary skill in the art to have the barrel project upward at an angle between 45 to 10 degrees relative to the horizontal plane that contains the gripping index and middle fingers, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gamache et al. in view of Paul et al. (US 5,158,535).

In regard to Claim 12, Gamache et al. disclose the claimed invention except for the body and the plunger being made of paper or paper pulp to make the device disposable. Paul et al. disclose an applicator 10 for insertion of an object into the vagina (abstract, column 3, lines 34-39). The applicator has an elongate body 14, 16 having an

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elongate barrel 14, a gripping portion 20, a passage (extending from the hollow of enlarged portion 18 through the hollow of the plunger 16), a nonflowable object 12, and a plunger 16. Paul et al. teach that the applicator 10 may be made of cardboard (paper or paper pulp) in order to make it flushable (disposable) (column 7, lines 1-4). One would have been motivated to modify the applicator of Gamache et al. to be made out of paper or paper pulp as taught by Paul et al. since doing so would render the applicator disposable. Thus it would have been obvious to one of ordinary skill in the art to modify the applicator body and plunger of Gamache et al. to be manufactured from paper or paper pulp as taught by Paul et al. since doing so would render the applicator disposable.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grant. In regard to Claim 11, Grant discloses the claimed invention but does not expressly disclose that the barrel is of a material having a Shore A hardness between 40 and 80. However, Grant does disclose that the edges of the barrel may be pressed together, and it therefore flexible (Figs. 1-2; lines 29-35). The Shore A hardness of a material affects the flexibility of the material and is therefore considered to be a result effective variable. Thus, it would have been obvious to one of ordinary skill in the art to make the barrel from a material having a Shore A hardness between 40 and 80 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Holter (US 2,882,900), Reid (US 726,460), Anderson et al. (US 6,652,513 B1), Lamb (US 6,537,260 and US 2004/0236265).

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Keshia Gibson
Examiner, Art Unit 3761
klg 7/26/05

TATYANA ZALUKAEVA
PRIMARY EXAMINER

